

co/c



PATENT
ATTORNEY DOCKET NO.: 056291-5004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | | |
|------------------|-----------------------------|---|------------------|------|
| In re Patent No. | 6,774,122 |) | Confirmation No. | 5974 |
| Granted: | August 10, 2004 |) | | |
| Patentees: | John R. Evans <i>et al.</i> |) | | |
| Application No. | 09/756,291 |) | | |
| Filed: | January 9, 2001 |) | | |
| FOR: | FORMULATION |) | | |

Attention Certificate of Corrections Branch
Commissioner for Patents,
P.O. Box 1450,
Alexandria, VA 22313-1450

Date August 6, 2007

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR § 1.322

This is a request for the issuance of a Certificate of Correction under 37 C.F.R. 1.322 in the above-referenced patent. Two (2) copies of form PTO-1050 are enclosed. The complete Certificate of Correction involves one (1) page.

It is requested that the above patent be corrected as shown in the attached proposed Certificate of Correction to correct printing errors that occur in claims 5 and 6. In claim 5, line 2 (column 13, line 8) "brass" should be corrected to read --breast--; and in claim 5, line 10 (column 13, line 16) "mgml" should be corrected to read --mgml^l--. In claim 6, line 4 (column 14, line 4) "mgm^l" should be corrected to read --mgml^l--.

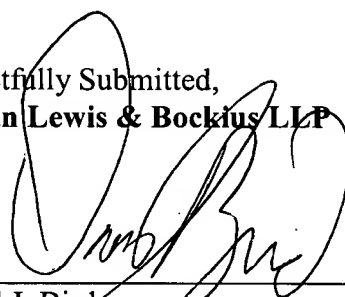
These errors in claims 5 and 6 occurred in the printing of the patent. This is clear from a comparison of claims 28 and 45 presented with the Supplemental Amendment After Final filed January 30, 2004, against corresponding granted patent claims 5 and 6. A copy of the claims from this Supplemental Amendment from PAIR (showing the corresponding patent numbers) is attached for the Examiner's convenience.

As the errors identified in the above-referenced U.S. Patent occurred through the fault of the U.S. Patent and Trademark Office, correction under 37 C.F.R. 1.322 is respectfully corrected, and no fee is enclosed. However, if there are any additional fees due in connection with the

AUG 8 2007

filing of this Request, the Commissioner is hereby authorized to charge any fees due to Deposit
Account No. 50-0310.

Respectfully Submitted,
Morgan Lewis & Bockius LLP

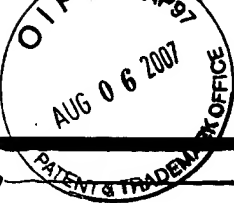


Date: August 6, 2007
Morgan Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel. No.: 202-739-3000
DJB:

By:

Donald J. Bird
Registration No. 25,323
Tel. No.: (202) 739-5320
Fax No.: (202) 739-3001

AUG 8 2007



JAN 30 2004 3:15 PM FR

TO 13950#562915004# P.06

ATTORNEY DOCKET NO.: 056291-5004

Application No.: 09/756,291

Page 2

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in this application:

Listing of Claims:

Claims 1-23 (cancelled)

11 Claim ~~24~~ (previously amended): A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5ngml^{-1} is attained for at least 2 weeks after injection.

2 Claim ~~25~~ (previously added): The method as claimed in claim ~~24~~ wherein the benign or malignant disease is breast cancer.

3 Claim ~~26~~ (previously added): The method as claimed in claim ~~24~~ wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection.

4 Claim ~~27~~ (previously added): The method as claimed in claim ~~24~~ wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks after injection.

5 Claim ~~28~~ (previously amended): A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle whereby the formulation comprises at least 45mgml^{-1} of fulvestrant.

L-WA/2105603.1

PAGE 6/9 * RCVD AT 1/30/2004 3:20:45 PM [Eastern Standard Time] * SVR:USPTO-EFXXF-1/2 * DNIS:8729306 * CSID: * DURATION (mm-ss):03-40

AUG 8 2007

JAN 30 2004 3:16 PM FR

TO 13950#562915004# P.07

ATTORNEY DOCKET NO.: 056291-5004

Application No.: 09/756,291

Page 3

Claims 29 - 44 (cancelled).

^{1 5}
6 Claim ~~45~~ (previously added): The method as claimed in claim ~~24~~ or ~~28~~ wherein the total volume of the formulation administered to said human is 6ml or less, and the concentration of fulvestrant in said formulation is at least 45mgml⁻¹.

^{1 5}
7 Claim ~~46~~ (previously added): The method as claimed in claim ~~24~~ or ~~28~~ wherein the total volume of the formulation administered to said human is 6ml or less, and the total amount of fulvestrant in said volume of formulation is 250mg or more.

⁷
8 Claim ~~47~~ (previously amended): The method as claimed in claim ~~46~~ wherein the total volume of the formulation is from 5 to 5.25ml, and the total amount of fulvestrant in said volume of formulation is 250mg.

Claim 48 - 50 (cancelled).

⁵
9 Claim ~~51~~ (new): The method as claimed in claim ~~28~~ wherein the benign or malignant disease is breast cancer.

1-WA/2105603.1

PAGE 7/9 * RCVD AT 1/30/2004 3:20:45 PM [Eastern Standard Time] * SVR:USPTO-EFXXRF-1/2 * DNIS:8729306 * CSID: * DURATION (mm-ss):03-40

AUG 8 2007

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTIONPage 1 of 1

PATENT NO. : 6,774,122
APPLICATION NO. : 09/756,291
ISSUE DATE : August 10, 2004
INVENTOR(S) : John R Evans, Rosalind U. Grundy

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13, line 8, "brass" should read --breast--; and line 16, "mgml" should read --mgml¹--.

Column 14, line 4, "mgm⁻¹" should read --mgml¹--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, 22313-1450. PLEASE DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 6,774,122
APPLICATION NO. : 09/756,291
ISSUE DATE : August 10, 2004
INVENTOR(S) : John R Evans, Rosalind U. Grundy

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13, line 8, "brass" should read --breast--; and line 16, "mgml" should read --mgml⁻¹--.

Column 14, line 4, "mgm⁻¹" should read --mgml⁻¹--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, 22313-1450. PLEASE DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

AUG 8 2007